

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

pplicant's or agent's file reference	FOR FURTHER ACTION See Notific Preliminar	cation of Transmittal of International y Examination Report (Form PCT/IPEA/416)	
SM-LUP-937	International filing date (day/month/year) 27.10.2003	th/year) Priority date (day/month/year) 29.10.2002	
OCTAN 03/00345			
sternational Patent Classification (IPC)	of boilt liational olders.		
Applicant			
LUPIN LIMITED et al.			
This international preliminary Authority and is transmitted to	examination report has been prepared by the applicant according to Article 36.	is International Preliminary Examining	
This REPORT consists of a	total of 4 sheets, including this cover sheet.		
also poor	ompanied by ANNEXES, i.e. sheets of the de e the basis for this report and/or sheets conta section 607 of the Administrative Instructions	escription, claims and/or drawings which have ining rectifications made before this Authority under the PCT).	
These annexes consist of a			
Basis of the opi	nent of opinion with regard to novelty, inventi f invention ement under Rule 66.2(a)(ii) with regard to n xplanations supporting such statement	ve step and industrial applicability ovelty, inventive step or industrial applicability;	
Basis of the opi	nent of opinion with regard to novelty, invention finvention ement under Rule 66.2(a)(ii) with regard to not explanations supporting such statement sents cited so in the international application vations on the international application	ovelty, inventive step or industrial applicability;	
Basis of the opi	nent of opinion with regard to novelty, invention invention ement under Rule 66.2(a)(ii) with regard to not explanations supporting such statement ents cited in the international application vations on the international application	ve step and industrial applicability ovelty, inventive step or industrial applicability; pletion of this report	
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I ⊠ Basis of the opin II ☐ Priority III ☐ Non-establishm IV ☐ Lack of unity of V ⊠ Reasoned state citations and e VI ☐ Certain docum VII ☐ Certain defect VIII ☐ Certain observious of the demand	nent of opinion with regard to novelty, invention finvention ement under Rule 66.2(a)(ii) with regard to n xplanations supporting such statement hents cited is in the international application vations on the international application Date of com 02.02.200	ovelty, inventive step or industrial applicability; pletion of this report	
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IN 03/00345

- V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- 1. Statement

Novelty (N)

Yes: Claims

1-18

No: Claims

19

Inventive step (IS)

Yes: Claims

1-18 19

No: Claims

Industrial applicability (IA)

Yes: Claims

1-19

No: Claims

2. Citations and explanations

see separate sheet

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

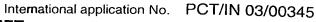
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1. With regard to the **elements** of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):

	Description, Pages						
	1-2	26	as originally filed				
	Cla	aims, Numbers					
	1-1	9	as originally filed				
2.	Wit lan	Vith regard to the language , all the elements marked above were available or furnished to this Authority in the inguage in which the international application was filed, unless otherwise indicated under this item.					
	The	hese elements were available or furnished to this Authority in the following language: , which is:					
		the language of a tr	anslation furnished for the purposes of the international search (under Rule 23.1(b)).				
			lication of the international application (under Rule 48.3(b)).				
		the language of a translation 55.2 and/or 55.	anslation furnished for the purposes of international preliminary examination (under .3).				
3.	With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:						
		contained in the inte	rnational application in written form.				
		filed together with th	e international application in computer readable form.				
		furnished subsequently to this Authority in computer readable form.					
		The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.					
		The statement that t listing has been furn	he information recorded in computer readable form is identical to the written sequence ished.				
4.	The	amendments have r	esulted in the cancellation of:				
		the description,	pages:				
		the claims,	Nos.:				
		the drawings,	sheets:				
5.		This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).					
		(Any replacement streport.)	neet containing such amendments must be referred to under item 1 and annexed to this				
S .	Additional observations, if necessary:						
			·				

INTERNATIONAL PRELIMINARY



EXAMINATION REPORT - SEPARATE SHEET

1) Reference is made to the following documents:

D1: US-A-4937330

- D2: Chemical Abstracts, Accession No. 2001:606938 (Zhu et al., Zhongguo Yiyao Gongye Zazhi, "Synthesis of ceftiofur" (2001), 32(6), 241-242)
- The subject-matter of present claims 19 is not new (Article 33(2) PCT). 2) In example 2 of D1 (see also claim 3) the HCl salt of ceftiofur is neutralized with PVP in aqueous THF and filtered to give the free amine (or free acid) in aqueous THF. The said solution is then added to an excess of sodium-ethyl hexanoate in aqueous THF. In view of the fact that sodium-ethyl hexanoate is the reactant and can also be regarded as organic base, the subject-matter of present claim 19 is not novel (the claim 19 does neither specify that the organic base is different from sodium-ethyl hexanoate nor that the transformation is a two-step procedure).
- The subject-matter of present claims 1-18 is new (Article 33(2) PCT; cf. below). 3)
- The subject-matter of claims 1-18 involves an inventive step (Article 33(3) PCT). 4)

D2 represents the closest prior art and discloses the preparation of ceftiofur from the same starting materials as the present application. The present claim 1 differs from the process of D2 in that the reaction medium

comprises water.

The technical problem underlying the present application is seen in the provision of an improved method for manufacture of ceftiofur (cf. page 1, lines 3/4, of the application).

In view of the fact that the applicant has submitted comparative data showing that the claimed process represents an improvement over D2, inventive activity can be acknowledged (letter of 15.10.04).